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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,580

01/25/2007

David Grenville Holmes

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05/28/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,580	Applicant(s) HOLMES, DAVID GRENVILLE	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I in the reply filed on 22 September 2008 is acknowledged.

Claims 7, 10, 11, 12, and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 22 September 2008.

Status of the Claims

Claims 1-6, 13 and 15 are pending for further prosecution on the merits.

Election/Restriction

As further required, Applicants elect for species (A) the combination of a DPP-IV inhibitor and an antiobesity agent. For species (B), Applicants elect (S)-l-{2-[5-cyanopyridin-2yl)amino]ethyl-aminoacetyl)-2-cyano-pyrrolidine. For species (C), Applicants elect orlistat; and for species (D), Applicants elect Type 2 diabetes mellitus and related diseases, disorders or conditions.

The claims have been examined to the extent that they read on the elected specie

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madar et al. in view of Balkan et al. (USPGPUB 2003/0139434 [WO01/52825]).

Madar et al. teach compounds (specifically drawn to claims 1-4 and 6) which inhibit dipeptidyl peptidase IV (DPP-IV) and are useful for the prevention or treatment of diabetes,

Art Unit: 1617

especially **type II diabetes**, as well as hyperglycemia, Syndrome X, hyperinsulinemia, obesity, atherosclerosis, and various immunomodulatory diseases (abstract only).

Madar et al. also teach [f]or the treatment of obesity, compounds of the present invention may be used alone, or in combination with any existing anti-obesity agent Agents which may be used in combination with the compounds of the present invention include, but are not limited to fatty acid uptake inhibitors such as **orlistat** and the like, monoamine reuptake inhibitors such as sibutramine and the like, anorectic agents such as dexfenfluramine, bromocryptine, and the like, sympathomimetics such as phentermine, phendimetrazine, mazindol, and the like, thyromimetic agents, or other such anti-obesity agents that are known to one skilled in the art [0293].

Madar et al. does not teach (S)-1-{2-[5-cyanopyridin- 2yl)amino]ethyl-aminoacetyl)-2-cyano-pyrrolidine, specifically.

However, Balkan et al. teach the DPP IV inhibitor (S)-1-{2-[5-cyanopyridin-2yl)amino]ethyl-aminoacetyl)-2-cyano-pyrrolidine and (S)-I -[(3-hydroxy-1-adamantyl)amino]acetyl-2- cyano-pyrrolidine (which is a comparable compound but was not elected).

Balkan et al. teaches combination therapy comprising a DPP IV inhibitor and at least one further diabetic compound.

Balkan et al. teach a treatment combination for obesity and for the cosmetic loss of body weight generally (please see entire abstract, especially the last 4 lines).

Art Unit: 1617

Balkan et al. teach (S)-1-((3-hydroxy-1-adamantyl)amino)acetyl-2-cyano-pyrrolidine and (S)-1-(2-(5-cyanopyridin-2-yl)amino)ethyl-aminoacetyl)-2-cyano-pyrrolidin are specifically claimed as the DPP-IV inhibitor. [...] are specifically claimed as the antidiabetic compounds (see paragraph 150).

Thus, it would have been *prima facie* obvious to the one of skill at the time of invention to recognize a reasonable expectation of success via the combining and incorporating together the teachings and modifications of Madar et al. and Balkan et al.

Madar et al. reasonably teach a combination comprising a DPP IV inhibitor with orlistat for the treatment of Type II diabetes. Balkan et al provide further motivation to combine based upon disclosing the actual elected compound of the invention. Balkan et al. does not expressly teach the combination with orlistat. However, it is reasonable to interpret that the embodiments of Balkan et al. are reasonably elucidated via the teachings and modifications of Madar et al. The inhibitors of Balkan et al. could reasonably be incorporated with the inhibitors of Madar et al. in direct obviousness over the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB
/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Application/Control Number: 10/579,580
Art Unit: 1617

Page 7